510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE INFORMATION

Date Prepared:	March 7, 2005
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Device Trade Name:	Verteview Anterior Cervical Plate System
Common Name:	Spinal Intervertebral Body Fixation Orthosis, Anterior Cervical Plate System
Regulatory Number:	888.3060
Classification:	Class II
Product Code:	KWQ

SUMMARY INTENDED USES/INDICATIONS

This system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (i.e., fractures or dislocation), 3) tumors, 4) spinal stenosis, 5) spondylolisthesis, 6)deformity or curvatures (i.e., kyphosis and/or lordosis, or scoliosis), 7) pseudoarthrosis, and/or 8) failed previous fusions.

WARNING: THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE.

SUMMARY DEVICE DESCRIPTION

The Verteview Anterior Cervical Plate System is a fixation device consisting of a variety of sizes of cervical plates, locking tabs, fixed and variable angle bone screws, and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using the anterior approach. Plates are offered in variable level configurations. Bone screws are available in various lengths. The screws have various diameters. All components are supplied clean not sterile.

The Verteview Anterior Cervical Plate System implant components are made from titanium alloy Ti-6Al-4V ELI. The plates and locking caps are treated with titanium anodization per AMS (Aerospace Material Specification) 2488 Type II. Bone screws are subjected to a color anodizing process to differentiate the screw type and diameter.

EQUIVALENT DEVICE

Testing in accordance with ASTM F1717-04 "Standard Test Methods for Spinal Implant Contructs in a Vertebrectomy Model" of the Verteview Anterior Cervical Plate System demonstrates that the device is substantially equivalent to the Synthes Spine Anterior CSLP System (K030866, concurrence date April 18, 2003) and the EBI Vue Lock Anterior Cervical Plate System (K010003, concurrence date January 31, 2001.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Ms. Leigh Cowden
CEO
Innovative Spinal Design, LLC
1555 Jupiter Park Drive, Suite 4
Jupiter, Florida 33458

Re: K050588
Trade/Device Name: Verteview Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 7, 2005
Received: March 9, 2005

Dear Ms. Cowden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as se forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050588

Device Name: Verteview Anterior Cervical Plate System

Indications for Use: This system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (i.e., fractures or dislocation), 3) tumors, 4) spinal stenosis, 5) spondylolisthesis, 6)deformity or curvatures (i.e., kyphosis and/or lordosis, or scoliosis), 7) pseudoarthrosis, and/or 8) failed previous fusions.

WARNING: THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050588